

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

INGENUS PHARMACEUTICALS, LLC,

Plaintiff,

v.

C.A. No. 24-1025-JLH

HETERO USA, INC., HETERO LABS LTD.,  
and HETERO LABS LTD. UNIT-VI,

Defendants.

**PLAINTIFF'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO STAY**

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## **I. NATURE AND STAGE OF THE PROCEEDINGS**

Plaintiff Ingenus Pharmaceuticals, LLC (“Ingenus”) filed this lawsuit on September 11, 2024, alleging that Defendants Hetero USA, Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit-VI. (“Hetero” or “Defendants”) infringe U.S. Patent No. 10,993,952 (“the ‘952 Patent”). (D.I. 1) A Scheduling Order has been entered (D.I. 20), the Parties Joint Claim Construction Chart is currently due on July 7, 2025 (*id.* at ¶ 10), with Ingenus’s opening claim construction brief due to be served on Hetero on July 21, 2025 (*id.* at ¶ 11). Claim construction briefing is currently scheduled to be completed on September 9, 2025 with the Joint Claim Construction Brief due to be filed no later than September 26, 2025. (*Id.*) The *Markman* hearing is currently scheduled for November 24, 2025. (*Id.* at ¶ 12)

In the coming month, during claim construction briefing, document production is scheduled to be substantially complete by July 31, 2025. (*Id.* at ¶ 7(b)). Trial in this matter is currently scheduled to begin on August 17, 2026, (*id.* at ¶ 21) and the 30-month stay in this litigation is scheduled to end on March 11, 2027, (*id.* at 14).

Ingenus has also asserted the ‘952 Patent in other litigation, including against Nexus Pharmaceuticals, Inc. in the Northern District of Illinois (“the Nexus Action”). *Ingenus Pharm., LLC v. Nexus Pharm., Inc.*, No. 1:22-cv-02868 (N.D. Ill.). On May 9, 2025, the Northern District of Illinois granted summary judgment, finding the ‘952 Patent to be invalid as indefinite and entering final judgment for Nexus and against Ingenus in that action. *Ingenus Pharm., LLC v. Nexus Pharm., Inc.*, No. 1:22-cv-02868, ECF No. 215, 216 (N.D. Ill. May 9, 2025); *see also Ingenus Pharm., LLC v. Nexus Pharm., Inc.*, 2025 WL 1359357 (N.D. Ill. May 9, 2025). A copy of that opinion is attached hereto. (**Exhibit A**) Ingenus has filed a Notice of Appeal in the Nexus action (the “Nexus Appeal”). *Ingenus Pharm., LLC v. Nexus Pharm., Inc.*, No. 1:22-cv-02868, ECF No. 219 (N.D. Ill. May 9, 2025). (**Exhibit B**)

To date, the Parties have been in discussions about staying aspects of this litigation to accommodate Hetero's proposal to file a summary judgment motion on the basis of collateral estoppel pursuant to the Scheduling Order. (D.I. 20 at ¶ 15) Despite initial progress, the Parties are at an impasse. (Rachuba Declaration<sup>1</sup> at ¶¶ 11–17) Hetero has since requested a status conference. (D.I. 48)<sup>2</sup> Ingenus presently moves to stay (the "Motion to Stay") this litigation pending resolution of the Nexus Appeal before the United States Court of Appeals for the Federal Circuit.

## II. SUMMARY OF ARGUMENT

1. Hetero's actions have effectively stayed discovery in this matter. This stay should continue pending resolution of the Nexus Appeal.

2. A stay will simplify issues for trial, because the Parties would only ask the Court to address collateral estoppel, should Hetero receive FDA approval during the pendency of the Nexus Appeal or prior to trial. Should Ingenus receive a favorable decision in the Nexus Appeal, collateral estoppel and the related issue of indefiniteness would not be an issue for the Court to address at trial.

3. Although a trial date has been set, discovery in this matter is not yet complete and is already effectively stayed at this point. The Parties have yet to depose witnesses or submit expert reports. In addition, the Parties have yet to brief claim construction.

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<sup>1</sup> The Declaration of L. Roman Rachuba, II ("Rachuba Decl.") is filed contemporaneously herewith.

<sup>2</sup> In this letter to the Court, and without Ingenus's permission or express approval, Hetero's counsel, Mr. Dorsney, misrepresented Ingenus's position on summary judgment. The next day, on June 11, 2025, Ingenus asked Delaware Counsel for Hetero to remove the statement attributed to Ingenus and correct this letter on the docket. Hetero refused that request. To be clear, **Ingenus does not oppose Hetero seeking leave** of the Court to file a summary judgment motion or to request a status conference in lieu of filing a motion for leave. (Rachuba Decl. at ¶ 16–17)

4. Hetero will not suffer undue prejudice from a stay. As above, fact discovery has yet to close, and no witnesses have been deposed. Ingenus proposes quarterly status updates to the Court, to *inter alia*, appraise the status of the Nexus Appeal, and Hetero's possible FDA approval prior to resolution of the Nexus Appeal. Should Hetero receive FDA approval and have an imminent planned or actual product launch, the Parties can notify the Court and request any emergency relief at that time.

### **III. STATEMENT OF FACTS**

On May 16, 2025, Hetero contacted Ingenus and requested that Ingenus stipulate to invalidity of the 952 Patent. (Rachuba Decl. at ¶ 11) At least since this date, discovery in this matter has been effectively stayed. (*Id.* at ¶¶ 2-9) Hetero continues to refuse all document production and responses to discovery requests, and has refused to meet and confer with Ingenus on these issues. (*Id.*) Notwithstanding Ingenus's efforts to do so, the Parties have not met and conferred on terms for the Joint Claim Construction Chart, which was scheduled to occur on May 27, 2025. (D.I. 20 at ¶ 10; 14) At the current pace of discovery, the Parties will be unable to meet current claim construction and document production deadlines. (Rachuba Decl. at ¶ 10)

At present, and to the best of Ingenus's knowledge, Hetero neither has Final nor Tentative Approval for its ANDA. (*Id.* at ¶ 19) Thus, even if Hetero's proposed summary judgment motion is successful, Hetero cannot market and sell its Cyclophosphamide Solution; 500mg/2.5ml (200mg/ml), 1gm/5ml (200mg/ml), and 2gm/10ml (200mg/ml) ("Defendants' ANDA Products"), at least until the FDA approves their Abbreviated New Drug Application ("ANDA") No. 219271. (D.I. 1, at ¶ 1)

### **IV. ARGUMENT**

Neither Ingenus nor Hetero seeks to continue this litigation at this point. Hetero's stated position (D.I. 48) is that it should be allowed to file a summary judgment motion. Ingenus seeks a

stay pending the Nexus Appeal. Therefore, neither of the Parties expects to reach trial as scheduled for August 2026. Should the Court grant final judgment in this litigation, an appeal of that final judgment would likely be joined with the Nexus Appeal, and therefore, could be remanded only upon a decision by the Federal Circuit in favor of Ingenus. For these reasons, and “assess[ing] *all* of the possible outcomes[,]” *Kaavo Inc. v. Cognizant Tech. Sols. Corp.*, 2015 WL 1737476, at \*2 (D. Del. Apr. 9, 2015) (emphasis in original) (citation omitted), should the Court grant a stay, there are three possible outcomes that would require the Court’s attention.<sup>3</sup> First, during the pendency of the Nexus Appeal, should Hetero receive FDA approval and plan to launch, this would require the Court to attend to the issues currently pending in the case, as well as the question of collateral estoppel that Hetero presently seeks to raise. Second, should the Federal Circuit decide in favor of Ingenus in the Nexus Appeal but prior to trial in this matter, if Hetero receives FDA approval and plans to launch, the Court would attend to the issues currently pending in the case. Third, should the Federal Circuit decide in favor of Ingenus, and this matter should reach trial prior to the FDA approving Defendant’s ANDA Products, the Court would address the issues currently pending in this case. For the reasons discussed below, the factors discussed below favor a stay pending resolution of the Nexus Appeal.

#### **A. Legal Standard**

“[T]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants.” *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936). “How this can best be done calls for the exercise of judgment, which must weigh competing interests and maintain an

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<sup>3</sup> Obviously, if the Federal Circuit rules against Ingenus in the Nexus Appeal, there would likely not be a trial.

even balance.” *Id.* at 254–55 (citations omitted). District courts have “broad power to stay proceedings.” *Bechtel Corp. v. Local 215, Laborers’ Int’l Union of N. Am., AFL-CIO*, 544 F.2d 1207, 1215 (3d Cir. 1976) (citing *Landis*, 299 U.S. at 254-55).

“Courts typically cite three factors that should guide the exercise of a court’s discretion when deciding whether a stay is appropriate[.]” *Enhanced Sec. Research, LLC v. Cisco Sys., Inc.*, 2010 WL 2573925, at \*3 (D. Del. June 25, 2010). These are (1) whether a stay will simplify the issues for trial, (2) whether discovery is complete and a trial date has been set, and (3) whether granting a stay would cause the non-movant to suffer undue prejudice from any delay or allow the movant to gain a clear tactical advantage.<sup>4</sup> *Id.*

#### **B. A Stay Will Simplify Issues for Trial**

There are two possible outcomes of the Nexus Appeal: one in favor of Ingenus and one not in favor of Ingenus. In the case of the latter, there would be no trial. As to the former, resolution of the Nexus Appeal in favor of Ingenus will largely resolve the need to brief the alleged collateral estoppel issue. To the extent that Hetero’s indefiniteness defense is based on the same grounds raised in the Nexus Action, a resolution of the Nexus Appeal in favor of Ingenus will dispose of that issue. In addition, a stay will avoid the need for Ingenus to refile this case against Hetero. Should the Nexus Appeal be resolved in favor of Ingenus, after the stay, the case will be greatly simplified in comparison to the issues of indefiniteness and alleged collateral estoppel that have been raised at this point in time. Since a stay will simplify issues for trial, this factor favors a stay.

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<sup>4</sup> Delaware courts routinely apply these factors when staying patent litigation pending *ex parte* reexamination or *inter partes* review.



### **C. Discovery Is Not Complete**

The case schedule also favors a stay: claim construction is not complete, expert discovery has not begun, and no witnesses have been deposed.

Though discovery remains open, Hetero has refused to engage with Ingenus and discovery is already effectively stayed by Hetero's inaction in this regard. (Rachuba Decl. at ¶ 9) For example, Hetero has still not produced any "documents related to the research and development of its ANDA product," despite committing to do so in its April 25, 2025 Opposition (D.I. 42) to Ingenus's Discovery Motion (D.I. 39). (Rachuba Decl. at ¶ 2) Contrary to the Court's Order of April 28, 2025 (D.I. 43), Hetero has likewise failed to produce "an org chart with employee names" and documents concerning its Paragraph IV certification, and has failed to "update its discovery responses to expressly state whether it is withholding responsive information." (D.I. 43). (Rachuba Decl. at ¶¶ 3-4) Hetero has also not produced any samples of Defendant's ANDA Products. (*Id.* at ¶ 5) Moreover, Hetero has refused to respond to Ingenus's multiple requests to meet and confer on these issues. (*Id.* at ¶¶ 6-8) Assuming the appeal in the Nexus Action is resolved in Ingenus's favor, these discovery issues will still need to be resolved but can await that resolution. For these reasons, this factor favors a stay.

### **D. A Stay Will Not Unreasonably Prejudice Hetero**

Staying the litigation at this point will not unreasonably prejudice Hetero. Trial in this case is scheduled to begin August 17, 2026 and Hetero's 30-month stay does not expire until March 11, 2027. (D.I. 20). Hetero's ANDA No. 219271 has not received Final Approval from the FDA and it cannot commercialize its product until it does. In fact, FDA has not even issued a Tentative Approval of Hetero's ANDA, a notification from FDA that an application is otherwise approvable but for the 30-month stay. (Rachuba Decl. at ¶ 19) Moreover, Hetero's actions to date have

effectively stayed discovery, including claim construction. (Rachuba Decl. at ¶ 9) As a result, a continued, further stay of this case will not unreasonably prejudice Hetero.

For example, Ingenus proposes joint quarterly status updates to the Court. While the case is stayed, should Hetero receive FDA approval and a planned or actual product launch by Hetero is imminent, the parties can notify the Court, either in a status report, or the parties may request any emergency relief as necessary. Since Hetero will not be prejudiced, this factor favors a stay.

**V. CONCLUSION**

For the reasons stated above, all three factors favor a stay. Therefore, this matter should be stayed pending resolution of the Nexus Appeal.

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